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10/524,065	02/08/2005	Takaya Sugawara	KPO-TSC-P1/TK-80/US	4447

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OSTRAGER CHONG FLAHERTY & BROITMAN PC
570 LEXINGTON AVENUE
FLOOR 17
NEW YORK, NY 10022-6894

EXAMINER	
ELLIS, SUEZU Y	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,065	SUGAWARA ET AL.	
	Examiner	Art Unit	
	Suezu Ellis	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 February 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL REJECTION

Response to Arguments

Applicant's arguments filed May 12, 2008 have been fully considered but they are not persuasive.

With respect to claims 6-9, applicant argues unexpected results by using the claimed laminated structure. However, the showing is not commensurate in scope with the claims. The examples fail to demonstrate the laminate structure comprising a polyethylene terephthalate film, a flexible polymer film, and a non-woven or woven fabric, as claimed. The examples only provide information regarding a laminate structure having a polyethylene terephthalate film and a low-density polyethylene film. The examples do not include the non-woven or woven fabric in the laminate structure. Further, the examples only illustrate the flexible polymer film being low-density polyethylene, and not for other polymers. Therefore, the showing is not representative of the whole scope of the claim. Thus, applicant's argument is not persuasive.

Regarding the USC 103(a) rejection, applicant's arguments with respect to claims 6-9 have been considered but are moot in view of the new ground(s) of rejection.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. The drawings demonstrate in Fig. 1, the backing having two layers, however the drawings do not illustrate three layers (it

does not illustrate the polyethylene terephthalate film). Therefore, the combination of a polyethylene terephthalate film, flexible polymer film and non-woven or woven fabric must be shown or the feature(s) canceled from the claim(s) (claims 6 and 7). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The specification describes the drug non-adsorptive layer made of polyethylene terephthalate film, and the flexible film can include woven or non-woven fabrics or polymer films (pg. 17, line 17 – pg. 18, line 27). However, the specification also discloses the laminate structure comprises a polyethylene terephthalate film and a flexible film or a non-woven fabric or a woven fabric (pg. 6, lines 27-29). Therefore, it is unclear from the specification, what the laminated structure is.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With respect to claims 6 and 7, the specification describes the backing having two layers: a flexible film and a drug non-adsorptive layer. The specification also discloses the laminate structure comprises a polyethylene terephthalate film and a

flexible film or a non-woven fabric or a woven fabric (pg. 6, lines 27-29). The specification does not appear to describe the backing having a polyethylene terephthalate film, a flexible polymer film, and a non-woven/woven fabric. The specification does not appear to clearly describe the flexible film being a combination of polymer and a non-woven/woven fabric. Therefore, the laminated structure comprising a polyethylene terephthalate film, a flexible polymer film, and a non-woven/woven fabric is considered new matter.

Claims 8 and 9 fail to comply with the written description requirement due to their dependency.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 6 and 7, claim language recites "the backing is a laminate structure comprising a polyethylene terephthalate film..., a flexible polymer film and a non-woven or woven fabric having a thickness of 1 to 200 μm". It is unclear if the flexible polymer film is the polyethylene terephthalate film, or a different film. If the flexible polymer film is different than that polyethylene terephthalate film, claim language needs to better distinguish the two polymer films. It is unclear if the backing has 3 layers (polyethylene terephthalate film, flexible polymer film, and a woven or non-woven

fabric), or if it has 2 layers (polyethylene terephthalate film and a flexible polymer film or a woven/non-woven fabric). Or does applicant mean the flexible film is a combination of both a polymer and a non-woven/woven fabric. Please clarify. Further, it is unclear if each of the flexible polymer film and the non-woven/woven fabric has a thickness of 1 to 200 μm, or if the claimed thickness range is for the combination of the flexible polymer film and non-woven/woven fabric. Please clarify. For examination purposes, claim language will be interpreted as the laminated structure comprises a) a polyethylene terephthalate film and b) a flexible polymer film or a woven fabric or a non-woven fabric.

Claims not specifically addressed are indefinite due to their dependency.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6 and 9/6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaji et al. (US 6,177,098) in view of Akemi et al. (US 5,242,951).

With respect to claim 6, Kawaji et al. discloses an external patch comprising a backing and a pressure-sensitive adhesive layer, wherein the backing is a laminate structure comprising a polyethylene terephthalate film and a non-woven fabric (col. 3, lines 25-33, 52-54). Kawaji et al. further discloses the polyethylene terephthalate film

has a thickness of 1.6 - 6.0 μm (col. 3, lines 48-55). Kawaji et al. further discloses the pressure-sensitive adhesive layer is made of an acrylic pressure-sensitive adhesive comprising estradiol, crotamiton and oleic acid (example 2) in the claimed ranges. Kawaji et al. further discloses using isocyanate-based crosslinking agents (col. 4, lines 52-53), however fails to expressly disclose the content amount of the isocyanate-based crosslinking agent. Akemi et al. teaches using 0.01-2% of an isocyanate-based crosslinking agent (col. 5, lines 17-18, 33-35), and more specifically in Example 3, 0.2% of an isocyanate-based crosslinking agent. It would have been obvious to one of ordinary skill in the art to modify the amount of crosslinking agent used in order to provide the desired aging time of the pressure-sensitive adhesive layer (col. 5, lines 30-32). Kawaji et al. also fails to expressly disclose the specific thickness of the non-woven fabric, however discloses the non-woven fabric has an appropriate thickness (col. 3, lines 27-33). Akemi et al. teaches a backing having a laminate structure comprising a polyester film having a thickness of 1-25 μm and a porous film having a thickness of 1-200 μm (col. 2, lines 54-65). It would have been obvious to one of ordinary skill in the art to modify the thickness of the non-woven fabric in order to prevent diffusion of the drug and maintain good handling properties, as desired (Kawaji: col. 3, lines 27-33). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claim 9/6, the modified Kawaji et al. discloses the acrylic-based pressure-sensitive adhesive comprises 2-ethylhexyl acrylate (col. 4, lines 44-45; example 2).

Claim 8/6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaji et al. in view of Akemi et al. and further in view of Radloff et al. (WO 2002/038134). US 2004/0091521 will be used herein as an English equivalent translation of WO 2002/038134.

With respect to claim 8/6, the modified Kawaji et al. addresses all the limitations of claim 6, however fails to expressly disclose the flexible polymer film being a low density polyethylene. Radloff et al. discloses a backing having a laminate structure comprising polyethylene terephthalate and a flexible film made of low density polyethylene [0060]. It would have been obvious to one of ordinary skill in the art to modify the materials of the backing of Akemi et al. to be that of Radloff et al. in order to provide the desired barrier effect and elasticity/flexibility [0054]-[0058], [0060].

Claims 6 and 9/6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Akemi et al. in view of Kawaji et al.

With respect to claim 6, Akemi et al. discloses an external patch comprising a backing (substrate) and a pressure-sensitive adhesive layer (col. 2, lines 30-65), wherein the pressure-sensitive adhesive layer is made of an acrylic pressure-sensitive adhesive (crosslinked gel layer having acrylate polymer) (col. 3, lines 30-48) containing

0.01 to 2% by weight of an isocyanate-based crosslinking agent (col. 5, lines 17-20, 33-35) and containing 1 to 6% by weight of a female hormone (estradiol) as an active ingredient (col. 5, lines 40-52), and oleic acid (col. 4, lines 34, 44). Example 3 in col. 7 demonstrates an example that comprising 2.5% estradiol and 0.2 % isocyanate crosslinking agent, therefore anticipates applicants' ranges of 0.01 to 2% by weight of an isocyanate-based crosslinking agent and 0.5 to 10% by weight of a female hormone (estradiol). The adhesive is considered to be pressure-sensitive since it is made of the same material as that of the applicant. Akemi et al. further discloses the backing is a laminate structure comprising a polyester film having a thickness of 0.1-10 μm and a woven or nonwoven fabric having a thickness of 1-200 μm (col. 2, lines 30-65).

Akemi et al. fails to expressly disclose the polyester film being polyethylene terephthalate. Akemi et al. also fails to expressly disclose the oleic acid being in the claimed range, however does teach using various ranges of oleic acid (col. 4, lines 50-55). Akemi et al. also fails to expressly disclose the inclusion of crotamiton and the quantity used. Akemi et al. also fails to expressly disclose the polyester Kawaji et al. discloses a formulation for a pressure-sensitive adhesive layer comprising oleic acid and crotamiton in an amount within the claimed range (Example 2). Kawaji et al. further discloses using polyethylene terephthalate as the polyester film of the backing (col. 3, lines 52-53). It would have been obvious to one of ordinary skill in the art to modify the material of the polyester to be polyethylene terephthalate since it is already widely used and is known to be safe on the living body (col. 3, lines 52-55). It would have been obvious to one of ordinary skill in the art to include crotamiton and to modify the quantity

of oleic acid and crotamiton in order to improve the absorption of the drug (Akemi: col. 4, lines 29-33; Kawaji: col. 1, lines 59-61). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

With respect to claim 9/6, the modified Akemi et al. discloses the acrylic pressure-sensitive adhesive comprises 2-ethylhexyl acrylate (col. 3, line 46).

Claim 8/6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Akemi et al. in view of Kawaji et al. and further in view of Radloff et al.

With respect to claim 8/6, the modified Akemi et al. addresses all the limitations of claim 6, however fails to expressly disclose the flexible polymer film being a low density polyethylene. Radloff et al. discloses a backing having a laminate structure comprising polyethylene terephthalate and a flexible film made of low density polyethylene [0060]. It would have been obvious to one of ordinary skill in the art to modify the materials of the backing of Akemi et al. to be that of Radloff et al. in order to provide the desired barrier effect and elasticity/flexibility [0054]-[0058], [0060].

Claims 7 and 9/7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xia et al. (US 5,693,335) in view of Hoffmann et al. (US 5,393,529) and further in view of Muraoka et al. (US 5,876,745).

With respect to claim 7, Xia et al. discloses an external patch comprising a backing and a pressure-sensitive adhesive layer, wherein the pressure-sensitive

adhesive layer is made of an acrylic pressure-sensitive adhesive containing a crosslinking agent, 0.5-10% by weight of isopropyl myristate as a distribution coefficient control agent (skin permeation enhancer) and 0.2-6% of norethindrone (equivalent to noresthisterone) as an active ingredient (col. 2, lines 17-27, 34-59; col. 3, lines 28-30, 39-50), therefore the content amount of the ingredients can fall in the claimed range. It would have been obvious to one of ordinary skill in the art to modify the quantity for each ingredient in order to optimize the desired medicinal benefits. Further, it has been held that discovering an optimum or working ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233. Xia et al. also discloses examples of the crosslinking agents used are in Hoffman et al. Hoffman et al. discloses norethisterone-containing transdermal systems utilizing isocyanate-based crosslinking agents (col. 3, lines 43-54; col. 5, line 55). However, Xia et al. fails to expressly disclose the amount of crosslinking agent used. Muraoka et al. teaches it is well known to utilize 0.35% of an isocyanate-based crosslinking agent (Examples 2 and 8). It would have been obvious to one of ordinary skill in the art to modify the crosslinking agent to be isocyanate-based in order to provide the desired reactivity and handling properties (col. 5, lines 1-25).

Xia et al. further discloses the backing is a laminate structure comprising one or more polymer layers and metal foil, wherein the polymer is polyethylene terephthalate (col. 3, lines 39-50), however fails to expressly disclose the polyethylene terephthalate film having a thickness of 0.1-10 μm and the inclusion of a flexible polymer film or a woven or nonwoven fabric having a thickness of 1-200 μm. Muraoka et al. discloses an external patch with a backing (support) having a laminate structure comprising a

polyester film having a thickness of 0.1-10 μm and a woven or nonwoven fabric having a thickness of 1-200 μm (col. 6, lines 25-66). It would have been obvious to one of ordinary skill in the art utilize the laminate structure of Muraoka et al. in order to provide an improved anchoring effect (col. 7, lines 39-47; col. 1, line 58 - col. 2, line 5).

With respect to claim 9/7, the modified Xia et al. discloses the acrylic pressure-sensitive adhesive comprises 2-ethylhexyl acrylate (col. 2, line 41).

Claim 8/7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Xia et al. in view of Hoffmann et al. and further in view of Muraoka et al. and further in view of Radloff et al.

With respect to claim 8/7, the modified Xia et al. addresses all the limitations of claim 7, however fails to expressly disclose the flexible polymer film being a low density polyethylene. Radloff et al. discloses a backing having a laminate structure comprising polyethylene terephthalate and a flexible film made of low density polyethylene [0060]. It would have been obvious to one of ordinary skill in the art to modify the materials of the backing of Xia et al. to be that of Radloff et al. in order to provide the desired barrier effect and elasticity/flexibility [0054]-[0058], [0060].

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suezu Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615